

SUBSTITUTE FORM PTO-1449
(MODIFIED)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
FR 07340/044002SERIAL NO.
09/265,191

MAY 06 1999

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use several sheets if necessary)

APPLICANT:
Carson, et al.FILING DATE
03/10/99GROUP
N/A

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER							ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
QN	AA	5	2	8	6	3	6	5	12/07/93	Rudolph, et al.	514/44	44	
	AB	5	2	7	6	0	1	9	01/04/94	Cohen, et al.	514/44	44	
	AC	5	2	7	8	3	0	2	01/11/94	Caruthers, et al.	536/24.5	24.5	
	AD	5	4	5	3	4	9	6	09/26/95	Caruthers, et al.	536/24.5	24.5	
	AE	3	7	2	5	5	4	5	04/03/73	Maes	424/480	180	
	AF	3	9	0	6	0	9	2	09/16/75	Hilleman, et al.	424/89	89	
QN	AG	1	2	3	4	7	1	8	Filed: 09/15/69	Hilleman, et al.			

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
QN	AH	0 468 520 A2	29.01.92	European Patent Office				
	AI	WO 95/26204	5 Oct 95	PCT				
	AJ	PCT/US95/03547	09 June 95	Internation Search Report PCT				
	AK	WO 98/18810	7 May 1998	PCT				
QN	AL	WO 96/02555A1	1 Feb 1996	PCT				

OTHER DOCUMENTS (including Author, Title, Date, Place of Publication)

QN	AM	Delphine J. Lee et al., "Inhibition of IgE Antibody Formation by Plasmid DNA Immunization Is Mediated by Both CD4+ and CD8+ T Cells", 1996, Int'l Archives of Allergy and Immunology 113/1-3/97
	AN	Yamamoto, "Mode of Action of Oligonucleotide Fraction Extracted From Mycobacterium Bovis BCG", National Institute of Health, 1994 Tokyo Japan
	AO	"Biochemical and Biophysical Research Communications", September 30, 1993, Academic Press, Inc.
	AP	Sato, et al., "Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization", 1996, Science Vol 273
	AQ	Warren, "Adjuvants", 1992, XP-002058362
	AR	Eyal Raz, et al., "Cytokines and Inflammatory Mediators" Oct. 20, 1996, XP-002058356
	AS	Corry, et al., "Interleukin 4, but Not Interleukin 5 or Eosinophils, Is Required in a Murine Model of Acute Airway Hyperreactivity," 1996, The Rockefeller University Press, Vol. 183 January 1996
QN	AT	Pisetsky, et al., Immunological Properties of Bacterial DNA, Annals New York Academy of Sciences; pp. 152-163

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QW	BA	5	5	8	0	8	5	9	12/03/96	Felgner, et al.	514/44	44	
QW	BB	5	7	0	3	0	5	5	12/30/97	Felgner, et al.	514/44	44	
QW	BC												

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							YES	NO
QW	BD	WO 95/26204	5 Oct 1995	PCT				
	BE							

OTHER DOCUMENTS (including Author, Title, Date, Place of Publication)

QW	BF	Nakagawa, et al., "Immunotherapy of Allergic Diseases", Int Arch Allergy Immunol 1993						
	BG	Manickan, et al. "Enhancement of Immune Response to naked DNA Vaccine by Immunization with Transfected Dendritic Cells", 1997, Journal of Leukocyte Biology, Vol 61						
	BH	Meeting Report, "International Meeting on the Nucleic Acid Vaccines for the Prevention of Infectious Disease and Regulating Nucleic Acid (DNA) Vaccines", 1996, Natcher Conference Center NIH						
	BI	Pardoll, et al. "Exposing the Immunology of Naked DNA Vaccines" Baltimore, Maryland 21205						
	BJ	"Bacterial DNA Causes Septic Shock", Nature, Vol 386, 27 March 1997						
	BK	Hohlfeld, et al. "The Immunobiology of Muscle" Immunology Today, Vol. 15 1994						
	BL	Ballas, et al. "Induction of NK Activity in Murine and Human Cells by CpG Motifs in Oligodeoxynucleotides and Bacterial DNA" XP-002058359, The American Association of Immunologists, 1996						
	BM	Branda, et al. "Amplification of antibody production by phosphorothioate oligodeoxynucleotides" XP-002058361, 1996 by Mosby-Year Book, Inc.						
	BN	Raz, et al. Preferential induction of a Th1 immune response and inhibition of specific IgE antibody formation by plasmid DNA immunization" Proceedings of the National Academy of Sciences of the United States of America" May 14, 1996, Vol. 93/Number 10						
	BO	Fuller, et al. "A Qualitative Progression in HIVType 1 Glycoprotein 120-Specific Cytotoxic Cellular and Humoral Immune Responses in Mice Receiving a DNA-Based Glycoprotein 120 Vaccine," AIDS Research and Human Retroviruses, Vol. 10, Nov. 1994						
	BP	Feltquate, et al. "Different T Helper Cell Types and Antibody Isotypes Generated by Saline and Gene Gun DNA Immunization" The Journal of Immunology, 1997 The American Association of Immunologists						
QW	BQ	Lee, et al. "Inhibition of IgE Antibody Formation by Plasmid DNA Immunization Is Mediated by both CD4+ and CD8+ T Cells, 1996, Salzburg, Austria						

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	CA						
	CB						
	CC						

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		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	CD							
	CE							
	CF							

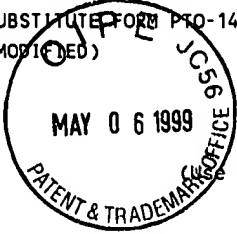
OTHER DOCUMENTS (including Author, Title, Date, Place of Publication)

QW	CG	Raz, et al. "Intradermal gene immunization: The possible role of DNA uptake in the induction of cellular immunity to viruses" Medical Sciences, September 1994						
	CH	Mader, et al. "A steroid-inducible promoter for the controlled overexpression of cloned genes in eukaryotic cells," Biochemistry, Vol. 90, pp 5603-5607, June 1993						
	CI	Kemeny, et al. "CD8+ T cells in allergy," Basic Review Article, 1992						
	CJ	Secrist, et al. "Allergen Immunotherapy Decreases Interleukin 4 Production in CD4+ T Cells from Allergic Individuals," The Rockefeller University Press, December 1993						
	CK	Multi-Test Directions for Use, New York 11050						
	CL	Terr, "Allergy Desensitization," Chapter 56, pp. 739 743						
	CM	Nakagawa, et al. "Immunotherapy of Allergic Diseases," Int Arch Allergy Immunol, 1993						
	CN	Davis, et al. "Plasmid DNA Is Superior to Viral Vectors for Direct Gene Transfer into Adult Mouse Skeletal Muscle," Human Gene Therapy, 4:733-740						
	CO	Ramsay, et al. "Enhancement of Mucosal IgA Responses by Interleukins 5 and 6 Encoded in Recombinant Vaccine Vectors," Reproduction, Fertility and Development, Australia, 1994						
	CP	Mojcik, et al. "Administration of a Phosphorothioate Oligonucleotide Antisense to Murine Endogenous Retroviral MCF env Causes Immune Effects in Vivo in a Sequence-Specific Manner," Clinical Immunology and Immunopathology, Vol. 67, 1993						
QW	CQ	Messina, et al. "The Influence of DNA Structure in the In Vitro Stimulation of Murine Lymphocytes by Natural and Synthetic Polynucleotide Antigens ¹ ," Cellular Immunology, Vol 147, March 1993						

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		INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)					
		APPLICANT: Carson, et al.				FILING DATE 03/10/99	
(37 CFR 1.98(b))							

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	DA						
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							YES	NO
	DD							
	DE							

OTHER DOCUMENTS (including Author, Title, Date, Place of Publication)

QN	DF	Messina, et al. "Stimulation of In Vitro Murine Lymphocyte Proliferation by Bacterial DNA ¹ ," The Journal of Immunology, 75th Anniversary, Vol 147, September 1991						
	DG	Yamamoto, et al. "Unique Palindromic Sequences in Synthetic Oligonucleotides are Required to Induce INF and Augment INF-Mediated Natural Killer Activity ¹ ," The Journal of Immunology, Vol 148, June 1992						
	DH	Tanaka, et al. "An Antisense Oligonucleotide Complementary to a Sequence in Iy2b Increases y2b Germline Transcripts, Stimulated B Cell DNA Synthesis, and Inhibits Immunoglobulin Secretion," The Journal of Experimental Medicine, The Rockefeller University Press, Vol 175, 1992						
	DI	Krieg, "CpG DNA: A Pathogenic Factor in Systemic Lupus Erythematosus?" Journal of Clinical Immunology, Plenum Press, New York and London, Vol 15, January 1995						
	DJ	Jachimczak, et al. "The effect of transforming growth factor -B2-specific phosphorothioate-anti-sense oligodeoxynucleotides in reversing cellular immunosuppression in malignant glioma," Journal of Neurosurgery, April 1993, Vol 78						
	DK	Krieg, et al. "CpG Motifs in bacterial DNA trigger direct B-cell activation," Nature International Weekly Journal of Science, Vol 374, No. 6522, April 1995						
	DL	Jyonouchi, et al. "Immunomodulating Actions of Nucleotides: Enhancement of Immunoglobulin Production by Human Cord Blood Lymphocytes," Pediatric Research, Vol 64, August 1993						
	DM	Pisetsky, et al. "Stimulation of Murine Lymphocyte Proliferation by a Phosphorothioate Oligonucleotide with Antisense Activity for Herpes Simplex Virus," Life Sciences, 1993						
QN	DN	Iguchi-Ariga, et al. "CpG methylation of the cAMP-responsive enhancer/promote sequence TGACGTCA abolishes specific factor binding as well as transcriptional activation," Genes & Development, 1989						

EXAMINER	<i>Quang Nguyen</i>	DATE CONSIDERED	01/07/02
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	EA						
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							YES	NO
	ED							
	EE							

OTHER DOCUMENTS (including Author, Title, Date, Place of Publication)

QW	EF	Krieg, et al. "A Role for Endogenous Retroviral Sequences in the Regulation of Lymphocyte Activation," The Journal of Immunology, Vol 143, 1989						
	EG	Ewel, et al. "Polyinosinic-Polycytidylic Acid Complexed with Poly-L-lysine and Carboxymethylcellulose in Combination with Interleukin 2 in Patients with Cancer: Clinical and Immunological Effects ¹ ," Cancer Research, June 1992						
	EH	Sano, et al. "Binding Properties of Human Anti-DNA Antibodies to Cloned Human DNA Fragments," Immunology, 1989						
	EI	Nishida, et al. "Definition of a GC-rich motif as regulatory sequence of the human IL-3 gene: coordinate regulation of the IL-3 gene by CLE2/GC box of the GM-CSF gene in T cell activation," International Immunology, Vol 3, 1991						
	EJ	Bennett, et al. "DNA Binding to Human Leukocytes," The American Society for Clinical Investigation, Inc., Dec. 1985						
	EK	Robinson, et al. "Use of direct DNA inoculations to elicit protective immune responses," Journal of Cellular Biochemistry, March 1993						
	EL	Ulmer, et al. "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," Science, Vol 259, March 1993						
	EM	Kimura, et al. "Binding of Oligodeoxynucleotides to Scavenger Receptors Is Required for Oligodeoxynucleotides to Augment NK Cell Activity and Induce IFN," J. Biochem, Vol 116, 1994						
	EN	Yamamoto, et al. "Ability of Oligonucleotides with Certain Palindromes to Induce Interferon Zproduction and Augment Natural Killer Cell Activity Is Associated with Their Base Length," Antisense Research and Development, 1994						
	EO	Yamamoto, "Lipofection of Synthetic Oligodeoxyribonucleotide Having a Palindromic Sequence of AACGTT to Murine Splenocytes Enhances Interferon Production and Natural Killer Activity," Microbiol. Immunol. 38(10), 1994						
QW	EP	Yakubov, et al. "Mechanism of oligonucleotide uptake by cells: Involvement of specific receptors?" Proc. Natl. Acad. Sci. USA, September 1989						

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	FA						
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							YES	NO
	FD							
	FE							

OTHER DOCUMENTS (including Author, Title, Date, Place of Publication)

QW	FF	Schleimer, et al. "IL-4 Induces Adherence of Human Eosinophils and Basophils but not Neutrophils to Endothelium," The Journal of Immunology, 1992						
	FG	Zhao, et al. "Comparison of Cellular Binding and Uptake of Antisense Phosphodiester, Phosphorothioate, and Mixed Phosphorothioate and Methylphosphonate Oligonucleotides," Antisense Research and Development, Vol 3, Spring 1993						
	FH	Tam, et al. "Oligonucleotide-Mediated Inhibition of CD28 Expression Induces Human T Cell Hyporesponsiveness and Manifests Impaired Contact Hypersensitivity in Mice," The Journal of Immunology, Vol 158, January 1997						
	FI	Hawkins, et al. Editorial, "Toward Genetically Targeted Research and Therapeutics," Antisense Research and Development, 1992						
	FJ	Sedegah, et al., "Protection against malaria by immunization with plasmid DNA encoding circumsporozoite protein," Proc. Natl. Acad. Sci. USA, Vol. 91, pp. 9866-9870, October 1994, Immunology						
	FK	D. Xu, et al., "Protection against leishmaniasis by injection of DNA encoding a major surface glycoprotein, gp63, of L. Major," Immunology, 173-176; November 1994						
	FL	Pisetsky, et al., Immunological Properties of Bacterial DNA ^a , Annals New York Academy of Sciences, p. 152						
	FM	Whalen, et al., DNA-Mediated Immunization to the Hepatitis B Surface Antigen, DNA Vaccines A New Era in Vaccinology; The New York Academy of Sciences, Vol. 772; p. 64-77; 1995						
	FN	Pisetsky, et al., Immunological Properties of Bacterial DNA, The New York Academy of Sciences; Abstracts; p. 19; April 6-9, 1995						
QW	FO	Shiver, et al., Cytotoxic T Lymphocyte and helper T Cell Responses following HIV Polynucleotide Vaccination, DNA Vaccines A New Era in Vaccinology; The New York Academy of Sciences, Vol. 772; p. 198-209; 1995						

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	GC						

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							YES	NO
	GD							
	GE							

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QN	GF	Mor, et al., Complexity of the Cytokine and Antibody response Elicited by Immunizing Mice with Plasmodium yoelii Circumsporozoite protein Plasmid DNA ¹ , The Journal of Immunology; Vol. 155, No. 4; pp. 2039-2046; August 15, 1995						
	GG	Yi, et al., IFN-γ Promotes IL-6 and IgM secretion in Response to CpG Motifs in Bacterial DNA and Oligodeoxynucleotides, The Journal of Immunology; Vol. 156, No. 2; pp. 558-564 January 15, 1996						
	GH	Heather L. Davis, Plasmid DNA expression systems for the purpose of immunization, Expression Systems; pp. 635-640						
	GI	David S. Pisetsky, The Immunologic Properties of DNA ¹ , The Journal of Immunology; Vol. 156, No. 2; pp. 421-423 January 15, 1996						
	GJ	Chace, et al., Bacterial DNA-Induced NK Cell IFN-γ Production is Dependent on Macrophage Secretion of IL-12, Clinical Immunology and Immunopathology, Vol. 84, No. 2, August 1997; pp. 185-193						
	GK	MacFarlane, et al., Unmethylated CpG-containing oligodeoxynucleotides inhibit apoptosis in WEHI 231 B lymphocytes induced by several agents: evidence for blockade of apoptosis at a distal signaling step, Immunology 1997; 91; pp. 586-593						
	GL	Schwartz, et al., CpG Motifs in Bacterial DNA Cause Inflammation in the Lower Respiratory Tract, The Journal of Clinical Investigation; Vol. 100, No. 1; July 1997; pp. 68-73						
	GM	Chu, et al., CpG Oligodeoxynucleotides Act as Adjuvants that Switch on T helper 1 (Th1) Immunity, J. Exp. Med. The Rockefeller University Press; Vol. 186, No. 10; November 17, 1997; pp. 1623-1631						
QW	GN	Wooldridge, et al., Immunostimulatory Oligodeoxynucleotides Containing CpG Motifs Enhance the Efficacy of Monoclonal Antibody Therapy of Lymphoma, Blood, Vol. 89, No. 8; April 15, 1997; pp. 2994-2998						

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PTO/SB/96 (10-92)

Docket No. 24769/2028

CERTIFICATE UNDER 37 C.F.R. § 3.73(b)

In the application of: Dennis A. Carson et al. Patent No.:
 Serial No.: 09/265191 Issue Date:
 Filed: March 10, 1999
 For: RECOMBINANT GENE EXPRESSION VECTORS AND METHODS FOR USE OF SAME TO
 ENHANCE THE IMMUNE RESPONSE OF A HOST TO AN ANTIGEN

The Regents of the University of California, a university, certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of either:

A. ☐ An assignment from the inventor(s) of the patent application identified above. The assignment was recorded in the Patent and Trademark Office at Reel *, Frame *, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s) of the patent application identified above, to the current assignee as shown below:

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 To : *
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2. From : *
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3. From : *
 To : *
 The document was recorded in the Patent and Trademark Office at Reel *, Frame *, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☒ Copies of assignments or other documents in the chain of title are attached.

The undersigned has reviewed all the documents in the chain of title of the patent application identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above.

The undersigned (whose title is supplied below) is empowered to sign this certificate on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: July 7, 1999

Linda S. Stevenson
 Name: Linda S. Stevenson
 Title: Principal Prosecution Analyst

PTO/SB/96 (10-92)

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PATENT
ATTORNEY DOCKET NO. 024769-2028
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ASSIGNMENT

For good and valuable consideration, the receipt of which is hereby acknowledged, ASSIGNOR(S),

1. Dennis A. Carson
2. Eyal Raz
3. Mark Roman

hereby sells, assigns, and transfers to ASSIGNEE, The Regents of the University of California, a California Corporation, having its statewide administrative offices located at 1111 Franklin Street, 5th Floor, Oakland, California 94607-5200, and the successors, assigns and legal representatives of the ASSIGNEE all of its right, title and interest for the United States and its territorial possessions and in all foreign countries in and to, any and all improvements in the invention entitled:

RECOMBINANT GENE EXPRESSION VECTORS AND METHODS OR USE OF SAME TO ENHANCE THE IMMUNE RESPONSE OF A HOST TO AN ANTIGEN

and which is found in

- (a) ☐ U.S. patent application executed on _____, entitled as above and listing the above named persons as inventors.
- (b) ☒ U.S. patent application Serial Number 09/265,191, filed 3/10/99.
- (c) ☐ U.S. Patent No.: _____, issued _____.

And any legal equivalent thereof in a foreign country, including the right to claim priority and, in and to, all Letters Patent to be obtained for said invention by the above application or in any continuation, division, continuation-in-part, extension or substitute thereof, and any reissue, reexamination or extension of said Letters Patent and all rights under all International Conventions for the Protection of Industrial Property;

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ASSIGNOR(S) further covenants that ASSIGNEE will, upon its request, be provided promptly with all pertinent facts and documents relating to said invention and said Letters Patent and Legal equivalents as may be known and accessible to ASSIGNOR and will testify as to the same in any interference, litigation, or proceeding relating thereto and will promptly execute and deliver to ASSIGNEE or its legal representative any and all papers, instruments or affidavits required to apply for, obtain, maintain, issue or enforce said application, said invention and said Letters Patent and said equivalents thereof which may be necessary or desirable to carry out the purposes thereof. An attorney of record is authorized and requested by the execution of this assignment to insert into this assignment the filing date and serial number of said application when officially known.

AND the ASSIGNOR(S) requests the Commissioner of Patents and Trademarks to issue said Letters Patent of the United States and any reissue or extension thereof to the ASSIGNEE, The Regents of the University of California.

Executed this

Signature of Inventor(s)

25 day of June, 1999
25 day of June, 1999
25 day of June, 1999

Dennis A. Carson
Dennis A. Carson
Eyal Raz
Eyal Raz
Mark Roman
Mark Roman